REMARKS/ARGUMENTS

The Office Action mailed August 14, 2002, has been received and reviewed. Claims 1, 3, 10 through 20, 22, and 28 through 63 are currently pending in the application. Applicants affirm the election to prosecute the invention of Group I, Claims 1, 3, 10 through 13, 15, 16, 34 through 39, 41, 47, 53, 56, 59, 62, and 63. Claims 14, 17 through 20, 22, 28 through 33, 40, 42 through 46, 48 through 52, 54, 55, 57, 58, 60, and 61 are withdrawn from consideration as being drawn to non-elected invention(s). Claims 1, 3, 10 through 13, 15, 16, 34 through 39, 41, 47, 53, 56, 59, 62, and 63 stand rejected. Applicants have amended claims 3, 10-16, 34-39, 41, 47, 53, 56, and 59, and respectfully request reconsideration of the application as amended herein.

35 U.S.C. § 112 Claim Rejections

Claims 1, 3, 10 through 13, 15, 16, 34 through 39, 47, 59, 62, and 63 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended independent claims 1, 41, 53, and 56 to eliminate recitation to a narrower statement of the limitation "membrane polymer." Applicants have further amended claim 12 to recite "a drug containing chamber" and eliminate the lack of antecedent basis for the term. In view of the foregoing, Applicants respectfully request withdrawal of the rejections based on 35 U.S.C. § 112, second paragraph.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 5,728,396 to Peery et al. in View of U.S. Patent No. 5,446,108 to Jiang

Claims 1, 3, 10 through 13, 15, 16, 34 through 39, 41, 47, 53, 56, 59, 62, and 63 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Peery et al. (U.S. Patent No. 5,728,396) in view of Jiang (U.S. Patent No. 5,446,108). Applicants respectfully traverse this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The 35 U.S.C. § 103(a) obviousness rejections of claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56, 59, 62, and 63 are improper because the Examiner has not established a *prima facie* case of obviousness, has used hindsight reconstruction to argue obviousness, and because there is no suggestion to combine the references.

Amended independent claim 1 recites a rate controlling membrane for an implantable drug delivery device characterized by being subjected to an elevated temperature of about 30° C to about 5° C below the melting temperature of the membrane for a predetermined period of about 1-250 hours and subsequently incorporated into the delivery device. Amended independent claim 41 requires the rate controlling membrane for an implantable drug delivery device be subjected to an elevated temperature of about 52° C to about 72° C for a predetermined period of about 2 to 36 hours and subsequently incorporated into the delivery device. Amended independent claim 53 requires the rate controlling membrane for an implantable drug delivery device be subjected to an elevated temperature of about 45° C to about 80° C for a predetermined period of from about 1 to about 75 hours and subsequently incorporated into the delivery device. Amended independent claim 56 requires the rate controlling membrane for an implantable drug delivery device be to an elevated temperature of about 55° C - 75° C for a predetermined period of about 12 —48 hours wherein the membrane comprises a material selected from the group consisting of polyurethanes or polyether blocked amides copolymers. Thus, all of the pending independent claims require a rate controlling membrane for use in an implantable drug delivery device that is characterized by being subjected to particular temperatures for particular periods of

time, then subsequently being incorporated into the delivery device.

Peery et al. discloses water-swellable, semipermeable plugs 24 and 26 that are inserted into and engaged with the interior surface of a reservoir 12. (See Figs. 1 and 2; col. 4, lines 51-61). As acknowledged by the Examiner, "Peery et al. does not disclose that the rate controlling membrane (plugs 24 and 26) is subjected to an elevated temperature below the melting temperature for a predetermined time and annealed." (Office Action at pg. 8).

Jiang is relied upon as disclosing polyamide polymers used in the making of surgical devices such as drug delivery devices that are subjected to an annealing step. (Office Action at pg. 8). The Examiner also contends that the polyamide polymers are "subsequently incorporated into a delivery device." However, those sections relied upon in the Office action (col. 3, line 31 to col. 4, line 7 and col. 5, lines 14-50) do not teach or suggest that the polyamide polymers are "subsequently incorporated into a delivery device." Instead, those portions of Jiang teach the preparation and structure of the moldable/extrudable polymer as a filament for use as, *e.g.*, a suture. (see col. 3, line 31 to col. 4, line 7; and col. 5 lines 14-25). Other surgical articles of manufacture, such as staples, clips, pins, prosthetic devices, wound dressings, and screws, are also taught. (Col 5, lines 34-42). Any reference to drug delivery devices is limited to the phrase "drug delivery devices, as used herein, include any device or article of manufacture which is used to deliver a medicinal agent." (col. 5, lines 34-36). At best, while Jiang may arguably suggest using a particular copolymers for manufacture of drug delivery devices, it does not teach or suggest use of a rate controlling membrane for subsequent incorporation into a delivery device. Thus, it is respectfully submitted that Jiang does not teach or suggest use of polyamide polymers that are annealed and subsequently incorporated into a delivery device, as suggested in the Office Action.

In support of the obviousness rejection, the Office Action further states that Jiang discloses "that the membrane is annealed (see col. 4, lines 6-7) causing the membrane to shrink thereby returning the membrane to its most relaxed state which is equivalent to Applicant's use of the specific temperatures and time periods sued." (Office Action at pg. 9). However, the relied-upon portion of Jiang teaches the manufacture of a filament, specifically a monofilament

suture, by melt extruding the polymer to provide a monofilament and stretching the solidified monofilament at an elevated temperature to provide a stretched monofilament. (col. 3, line 65 to col. 4, line 5). The cited language does not teach or suggest the manufacture of a rate controlling membrane. The last portion of Jiang cited in the Office Action states that "the monofilament can be annealed to provide a finished suture." (col. 4, lines 5-7). As such, the cited language does no more than teach annealing a polymer to provide a finished surface on a suture. In contrast to the present invention, Jiang does not teach or suggest, alone or in combination with Peery et al., a rate controlling membrane that has been heated to particular temperatures for specific periods of time to (as described in the specification) effects a change in the morphology of the polymer that is stable at room temperature and which provides consistent membrane functionality over time. Jiang also does not teach or suggest that annealing the monofilament suture causes "the membrane to shrink thereby returning the membrane to its most relaxed state," as suggested in the Office Action.

In view of the foregoing, Applicants respectfully submit that Peery et al. and Jiang do not teach or suggest all of the claim limitations. Additionally, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings without relying on hindsight reconstruction or relying on the teachings of the present application. Applicants respectfully request that the obviousness rejections to pending claims 1, 3, 10 through 13, 15, 16, 34 through 39, 41, 47, 53, 56, and 59 be withdrawn.

Double Patenting Rejection Based on U.S. Patent No. 6,375,978 to Kleiner et al.

Claims 1, 3, 10 through 13, 15, 16, 34 through 39, 41, 47, 53, 56, 59, 62, and 63 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 1, 10 through 14, 16, and 35 of U.S. Patent No. 6,375,978 to Kleiner et al. In order to avoid further expenses and time delay, Applicants elect to expedite the prosecution of the present application by filing a terminal disclaimer to obviate the double patenting rejections in compliance with 37 CFR §1.321 (b) and (c). Applicants' filing of the

terminal disclaimer should not be construed as acquiescence of the Examiner's double patenting or obviousness-type double patenting rejections. Attached is the terminal disclaimer and accompanying fee.

Amendments to the Specification

The specification has been amended to correct typographical and grammatical errors. No new matter has been added to the application.

ENTRY OF AMENDMENTS

The amendments to claims 3, 10-16, 34-39, 41, 47, 53, 56, and 59 above should be entered by the Examiner because the amendments are supported by the as-filed specification and drawings and do not add any new matter to the application.

CONCLUSION

Claims 1, 3, 10-13, 15, 16, 34-39, 41, 47, 53, 56, and 59 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully submitted,

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Enclosures: Appendices A and B

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